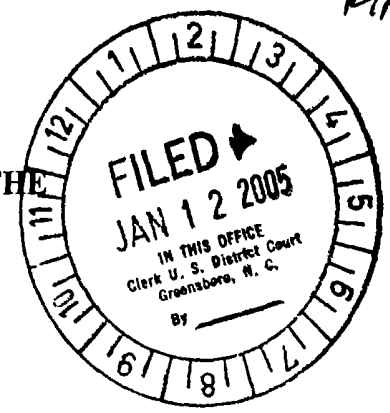

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PFIZER INC.,	)	
	)	
Plaintiff,	)	Civil Action No. ____
	)	
v.	)	
	)	
SYNTHON HOLDINGS BV; SYNTHON BV; SYNTHON PHARMACEUTICALS, LTD.; and SYNTHON LABORATORIES, INC.,	)	1:05CV00039
	)	
Defendants.	)	

COMPLAINT

Pfizer Inc. ("Pfizer"), by its attorneys, for its complaint against Synthon Holdings BV ("Synthon Holdings"), Synthon BV ("Synthon BV"), Synthon Pharmaceuticals, Ltd. ("Synthon Pharmaceuticals"), and Synthon Laboratories, Inc. ("Synthon Laboratories") (all four entities are referred to herein individually and collectively as "Synthon"), alleges as follows:

NATURE OF ACTION

1. This is an action by Pfizer against Synthon for infringement of United States Patent Nos. 4,572,909 (the "'909 patent") and 4,879,303 (the "'303 patent").

PARTIES, JURISDICTION AND VENUE

2. Pfizer is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York. Pfizer invests extensively in designing, developing, and testing and evaluating new and

innovative pharmaceutical products and it sells pharmaceutical products to the public throughout the United States.

3. Upon information and belief, Synthon Holdings and Synthon BV are related Netherlands companies with their headquarters at P.O. Box 7071, 6503 GN Nijmegen, Netherlands, and are the parent and the ultimate parent of the Synthon entities in this suit.

4. Upon information and belief, Synthon Pharmaceuticals is a corporation or a limited liability company organized and existing under the laws of the State of North Carolina and has its principal place of business at 6330 Quadrangle Drive #205, Chapel Hill, North Carolina.

5. Upon information and belief, Synthon Pharmaceuticals is a subsidiary of Synthon Holdings or Synthon BV, and is in the business of developing, testing, manufacturing and marketing generic pharmaceutical products, and is the main United States subsidiary or division of Synthon.

6. Upon information and belief, Synthon Laboratories is a corporation organized and existing under the laws of the Commonwealth of Virginia and has its principal place of business at 117 Loudoun Street SE # 201, Leesburg, Virginia. Upon information and belief, Synthon Laboratories is an affiliate, subsidiary or division of Synthon Pharmaceuticals or Synthon BV.

7. Upon information and belief, Synthon Laboratories assembled and caused to be filed with the United States Food and Drug Administration (the "FDA"), pursuant to 21 U.S.C. § 355(j)(2), Abbreviated New Drug Application No. 77-080 ("ANDA No. 77-080"), concerning a proposed drug product identified as "amlodipine besylate monohydrate" tablets in "2.5mg, 5mg & 10mg strengths of amlodipine" ("Synthon Amlodipine Besylate Tablets").

8. Upon information and belief, Synthon Holdings, Synthon BV or Synthon Pharmaceuticals, or all of the foregoing, caused, actively encouraged and/or directed Synthon Laboratories to file ANDA No. 77-080 with the FDA, and/or participated in the work related to the submission of ANDA No. 77-080.

9. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331 and 1338.

10. Defendants are subject to personal jurisdiction in this judicial district by reason of their presence in North Carolina, and on the basis of the presence and activity of their agents and alter egos.

11. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

FIRST CLAIM FOR RELIEF: INFRINGEMENT OF THE '909 PATENT

12. Pfizer realleges paragraphs 1 through 11 above as if fully set forth herein.

13. On February 25, 1986, the United States Patent and Trademark Office (the "PTO") issued to Pfizer the '909 patent, entitled "2-(Secondary Aminoalkoxymethyl) Dihydropyridine Derivatives as Anti-Ischaemic and Antihypertensive Agents," based on an application filed by Simon F. Campbell, Peter E. Cross, and John K. Stubbs, which had been assigned to Pfizer. Pfizer currently holds, and it continuously has held title to the '909 patent since it was issued.

14. The '909 patent discloses and claims, inter alia, a genus of dihydropridine compounds, including amlodipine, or their pharmaceutically acceptable acid addition salts, pharmaceutical compositions comprising the claimed compounds, and methods of treating ischaemic heart disease and hypertension by administering the claimed compounds.

15. Pfizer holds an approved New Drug Application for amlodipine besylate tablets, 2.5 mg, 5 mg and 10 mg dosage strengths, which it invented, developed and sells under the trade name Norvasc®. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, Pfizer listed the '909 patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to its Norvasc® drug product.

16. On December 6, 1993, the PTO issued a certificate extending the term of the '909 patent for 1,252 days, until July 31, 2006 (the "Patent Term Restoration"). The Norvasc® drug product is also entitled to six months of "pediatric exclusivity" pursuant to the provisions of 21 U.S.C. § 355a, and consequently the '909 patent's expiration date is January 31, 2007, and is so listed in the Orange Book.

17. On December 28, 2004, Pfizer received from Synthon Laboratories a "Notice of Paragraph IV Certification," dated December 23, 2004, stating that Synthon Laboratories had filed ANDA No. 77-080 with the FDA, seeking approval to market and sell its Synthon Amlodipine Besylate Tablets before the '909 patent's expiration date of January 31, 2007, as listed in the Orange Book ("Synthon's Notice Letter").

18. Synthon has infringed the '909 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 77-080, which includes the paragraph IV certification pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '909 patent, and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Synthon Amlodipine Besylate Tablets prior to the expiration of the '909 patent.

19. Upon information and belief, Synthon knowingly and willfully has infringed the '909 patent.

20. Pfizer will be irreparably harmed if Synthon is not enjoined from infringing the '909 patent.

SECOND CLAIM FOR RELIEF: INDUCING INFRINGEMENT OF THE '909 PATENT

21. Pfizer realleges paragraphs 1 through 20 above as if fully set forth herein.

22. Upon information and belief, Synthon Holdings, Synthon BV and Synthon Pharmaceuticals have infringed the '909 patent under 35 U.S.C. § 271(b) by actively inducing Synthon Laboratories to infringe the '909 patent.

THIRD CLAIM FOR RELIEF: INFRINGEMENT OF THE '303 PATENT

23. Pfizer realleges paragraphs 1 through 22 above as if fully set forth herein.

24. On November 7, 1989, the PTO issued to Pfizer the '303 patent, entitled "Pharmaceutically Acceptable Salts," based on an application filed by Edward Davison and James I. Wells, which had been assigned to Pfizer. Pfizer currently holds, and it continuously has held title to the '303 patent since it was issued.

25. The '303 patent discloses and claims inter alia, the besylate salt of amlodipine and oral and intravenous formulations comprising the besylate salt of amlodipine.

26. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, Pfizer listed the '303 patent in the Orange Book with respect to its Norvasc® drug product.

27. Pursuant to the provisions of 21 U.S.C. § 355a, the '303 patent is entitled to a six-month period of pediatric exclusivity and the '303 patent's expiration date is accordingly September 25, 2007, and is so listed in the Orange Book.

28. Synthon's Notice Letter also states that Synthon's ANDA No. 77-080, filed with the FDA, seeks approval to market and sell its Synthon Amlodipine Besylate Tablets before the '303 patent's expiration date of September 25, 2007.

29. Synthon has infringed the '303 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 77-080, which includes the paragraph IV certification pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '303 patent, and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Synthon Amlodipine Besylate Tablets prior to the expiration of the '303 patent.

30. Upon information and belief, Synthon has knowingly and willfully has infringed the '303 patent.

31. Pfizer will be irreparably harmed if Synthon is not enjoined from infringing the '303 patent.

FOURTH CLAIM FOR RELIEF: INDUCING INFRINGEMENT OF THE '303 PATENT

32. Pfizer realleges paragraphs 1 through 31 above as if fully set forth herein.

33. Upon information and belief, Synthon Holdings, Synthon BV and Synthon Pharmaceuticals have infringed the '303 patent under 35 U.S.C. § 271(b) by actively inducing Synthon Laboratories to infringe the '303 patent.

WHEREFORE, Pfizer requests the following relief:

1. A judgment in its favor providing that the effective date of any FDA approval for Synthon to make, use, sell, offer for sale, or import the Synthon Amlodipine Besylate Tablets described in ANDA No. 77-080 be no earlier than the date on which the '909 patent term, including the additional terms granted as the Patent Term Restoration and as the pediatric exclusivity period, expires, and no earlier than the date on which the '303 patent term, including the pediatric exclusivity period, expires;

2. A judgment in its favor permanently enjoining Synthon from making, using, selling, offering to sell, or importing into the United States the Synthon Amlodipine Besylate Tablets described in ANDA No. 77-080 until after expiration of the '909 patent term and the

'303 patent term, including the additional terms granted as the Patent Term Restoration and as the pediatric exclusivity period;

3. A judgment in its favor that defendants' infringement was willful;

4. A judgment in its favor for attorneys' fees incurred in pursuing this action pursuant to 35 U.S.C. § 285;

5. A judgment in its favor for costs and expenses incurred in pursuing this action; and

6. Such further and other relief as this Court may determine to be just and proper.

This the 12th day of January, 2005.

WOMBLE CARLYLE SANDRIDGE & RICE,
a Professional Limited Liability Company

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